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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,277	08/19/2003	Jean M. Gudas	ABGENIX.091A	6274

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EXAMINER

TUNGATURTHI, PARITHOSH K

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/644,277

Applicant(s)

GUDAS ET AL.

Examiner

Parithosh K. Tungaturthi

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 41-53 is/are pending in the application.
- 4a) Of the above claim(s) 42,43,45-48 and 53 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,41,44 and 51 is/are allowed.
- 6) ☒ Claim(s) 49,50 and 52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/10/03, 04/30/04, 09/07/04, 10/11/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The applicant has timely traversed the non-final rejection in the reply filed on 06/23/2006, and a response to the arguments is set forth.

2. Claims 3-40 have been cancelled

3. Claims 1, 2, 41, 44 and 51 have been amended.

4. Claims 1, 2, 41-53 are pending.

Claims 42, 43, 45-48 and 53 are withdrawn from further consideration under 37 C.F.R. 1.142(b) as being drawn to nonelected inventions.

5. Claims 1, 2, 41, 44, 49, 50 and 52 are under examination.

6. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior office action.

Objections withdrawn

7. The objection of claims 1 and 2 is withdrawn in view of amendments to the claims.

Rejections maintained and response to arguments

8. The rejection of claims 49, 50 and 52 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained for the reasons below.

The specification lacks complete deposit information for the deposit of the

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monoclonal antibodies 3.11.1 or 3.11.2. It is not clear that the monoclonal antibodies 3.11.1 or 3.11.2 are known and publicly available or can be reproducibly isolated from nature without undue experimentation.

Exact replication of an antibody is an unpredictable event. Although applicant has provided a written description of a method for selecting the claimed monoclonal antibodies, this method will not necessarily reproduce antibodies which are chemically and structurally identical to those claimed. It is unclear that one of skill in the art could derive a chimeric monoclonal antibody identical to those claimed. Undue experimentation would be required to screen all of the possible antibody species to obtain the claimed antibodies.

The applicant argues "courts have held that no deposit is required where the required biological materials can be MPEP 2404.02..... applicants provide both nucleic acid and amino acid sequence for the heavy and light chain of monoclonal antibody 3.11.1 in the specification as Monoclonal antibodies 3.11.1. and 3.11.12 are identical clones, thus a person of ordinary skill in the artcould obtain monoclonal antibodies 3.11.1 or 3.11.2 using publicly available And hence applicants respectfully submit that deposit of these antibodies is not required" (pages 5-6 of the response).

The above-arguments presented by the applicant are carefully considered but are not found persuasive.

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Although the amino acid sequence of the light and heavy chain variable region and constant light chain regions are disclosed, it is unclear if the entire amino acid sequence of the heavy chain hinge CH1, CH2, CH3 regions are given. Therefore, a suitable deposit for patent purposes is suggested. Without a publicly available deposit of the above cell line, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of: (1) the claimed cell line; (2) a cell line which produces the chemically and functionally distinct antibody claimed; and/or (3) the claimed antibody's amino acid or nucleic acid sequence is an unpredictable event.

Further, as pointed out by the applicant "one of ordinary skill in the antibody art" would know that very different V_H chains can combine with the same V_K chain to produce antibody-binding sites with nearly the same size, shape, antigen specificity, and affinity, and thus with given information in the disclosure would conclude that the claimed antibodies would require a deposit information.

Applicant's failure to refer to the deposit information pertaining to the monoclonal antibodies 3.11.1 or 3.11.2 in the specification is noted and it is required that the required deposit be made and all the conditions of 37 CFR 1.801-1.809 met.

If the deposit of the monoclonal antibodies 3.11.1 or 3.11.2 is not made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809 regarding availability and permanency of deposits, assurance of compliance is required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an

attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request:

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application:

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If a deposit is made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the biological material described in the specification as filed is the same as that deposited in the depository, stating that the deposited material is identical to the biological material described in the specification and was in the applicant's possession

at the time the application was filed.

Applicant's attention is directed to In re Lundak, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

Conclusion

9. Claims 1, 2, 41, 44 and 51 are found allowable.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parithosh K. Tungaturthi whose telephone number is

571-272-8789. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Parithosh K. Tungaturthi Ph.D.
(571) 272-8789



LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER